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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,676	10/16/2001	Eija Marjut Pirhonen	01942-00003	6631

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EXAMINER	
THOMPSON, CAMIE S	

ART UNIT	PAPER NUMBER
1774	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,676	PIRHONEN, EIJA MARJUT	
	Examiner	Art Unit	
	Camie S. Thompson	1774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Amendment filed 12/28/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-32 and 34-36* is/are rejected.

7)☒ Claim(s) *8 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and accompanying remarks filed December 28, 2005 have been acknowledged.

2. Examiner acknowledges amended claims 1, 3-5 and 11-12.

3. The rejection of claims 1, 15-16, 19-20, 29-30 and 34-36 under 35 U.S.C. 102(b) as being anticipated by Scheicher, U.S. Patent Number 4,278,630 is withdrawn due to applicant's amended claim 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Scheicher, U.S. Patent Number 4,278,630.

Scheicher discloses implants from ceramic substance having a porous surface, which stimulates ingrowth of bone tissue (see abstract). Additionally, the reference discloses that the ceramic substance can be in the form for fibers. Column 1, lines 43-59 of the reference discloses that the ceramic substances (fibers) are sintered together.

6. Claims 6-7 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO8604088.

The European reference discloses a carrier for immobilizing biologically active materials. The carrier comprises a porous, sintered glass fiber matrix (see abstract). Additionally, the reference discloses that an organic polymer holds the sintered glass fiber matrix together. The temperature in which the glass fibers are sintered is a process limitation within a product claim. Even though product-by-process claims are limited and defined by the process, determination of patentability is based on the product itself. The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product from the prior art, the claim is unpatentable even though it was made from a different process.

7. Claims 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO9847465.

The European reference discloses a porous composite for implants wherein the composite is comprised of bioactive material and non-bioactive material that is sintered together (see abstract). Additionally, the European reference discloses that the bioactive material is bioactive glass with a composition of 53-60% by weight of SiO_2; 0-34% by weight of Na_2O; 1-20% by weight K_2O; 0-5% by weight of MgO; 5-25% by weight of CaO; 0-4% by weight of B_2O_3 and 0.5-6% by weight of P_2O_5 (see reference claims 1, 5 and 6).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 3-6, 9-10, 15-26, 29-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO86-04088.

The European reference discloses a carrier for immobilizing biologically active materials. The carrier comprises a porous, sintered glass fiber matrix (see abstract). Additionally, the reference discloses that an organic polymer holds the sintered glass fiber matrix together. On page 4 of the reference, it is disclosed that the suitable temperature for sintering is 500-700 deg C. The reference does not provide the specific porosity of the composite. However, this is an optimizable feature. The porosity of the composite, the thickness of the polymer coating and the length of the fibers prior to sintering affect the immobilization of the biologically active material (see page 2 of the reference). Discovery of optimum values of a result effective variable involves only routine skill in the art *in re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art to have the porosity of the composite be in the range of 50-volume % to 90-volume %, a polymer coating thickness of about 1μm to about 200 μm and a length of the fibers prior to sintering be about 2 mm to about 30 mm in order to have a composite that immobilizes biologically active materials such as enzymes and microorganisms. The reference also discloses that the composite is in mold form. The last paragraph of page 2 of the reference discloses that the average diameter of the glass

fibers is within the range of 0.3-100 μm as per instant claims 19-20. The time in which the glass fibers are sintered is a process limitation within a product claim. Even though product-by-process claims are limited and defined by the process, determination of patentability is based on the product itself. The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product from the prior art, the claim is unpatentable even though it was made from a different process.

10. Claims 8 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not provide for the recited sintered scaffold material further including the biocompatible polymer coating being selected from the group consisting of polyglycolide, polylactide, poly-β-hydroxybutyric acid, polydioxanone, polyvinylacohol, polyesteramine, their copolymers and polymer blends thereof.

Response to Arguments

11. Applicant's arguments with respect to the instant claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Camie S. Thompson whose telephone number is (571) 272-1530. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena L Dye, can be reached at (571) 272-3186. The fax phone number for the Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RENA DYE
SUPERVISORY PATENT EXAMINER
A.U. 1774 3/20/04